



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
--------------------	-------------	-----------------------	---------------------

08/913,056 10/22/97 YAMAMOTO

N KP-8240

HM42/0609

ROBERT J. PATCH  
YOUNG & THOMPSON  
745 S 23RD ST  
SUITE 200  
ARLINGTON VA 22202

EXAMINER
----------

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED:

06/09/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/18/97

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-27 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-27 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

Art Unit: 1615

References in Japanese were considered only insofar as the abstracts provided.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazis et al in view of Roberts et al, Azria et al, Kissel et al, Japan 3-5427, EPA-215697, EPA 94157, and Cooper.

Mazis et al teach transdermal delivery comprising a permeation enhancer, a vasodilator, and an active (abstract). The active is any transdermally deliverable drug, including proteinaceous drugs such as insulin (column 3, lines 30-33, column 4, line 15).

Roberts teach particular vasodilators such as nitroglycerin, prostaglandins and calcium antagonists (column 8, lines 5-9).

Azria et al teach ~~taurocholic~~ <sup>taurocholic</sup> acid as an absorption enhancer for calcitonin. (Abstract).

Kissell et al teach salts of fusidic acid as enhancers for octreotide (Title).

Japan 3-5427 teaches glycyrrhizic acid as an absorption enhancer for calcitonin.

EPA 215697 teach acyl carnations <sup>itine</sup> as enhancers (abstract). Polypeptides are specified (page 4 lines 36-31).

EPA 94157 teaches cyclodextrin to increase absorption (abstract). Polypeptides are disclosed (page 3 line 13-page 6 line 2).

Cooper teaches acyl Azacyclo heptan<sup>e</sup>ones as enhancers (abstract). The enzyme asparaginase is disclosed as an active. (Column 20 line 18).

Art Unit: 1615

It would have been obvious to use the claimed unsodilators in <sup>the</sup> Mazis et al composition in view of Roberts et al and to use the particular claimed absorption enhancers in view of Azria et al, Kissler et al, Japan 3-5427 et al, EPA-215697, EPA 94157, and Cooper.

The examiner takes Judicial<sup>e</sup> notice concerning the remaining claimed enhancers.

Claims 3-6, 9-12, 14-16, 19, 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 3-6, 9-12, 14-16, 19 'one or more' is vague. Only one member should be chosen. A last member 'and mixtures thereof' is suggested.

In claim 20 Markush Language 'selected from...' is missing.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday-Friday from 9AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-5408.

Serial Number: 913056

Page 4

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2351.

Webman/sg

June 2, 1998

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500